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Thomas Richardson

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EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

05/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No. 10/058,835	Applicant(s) RICHARDSON ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,36,38,40,42 and 46-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33, 36, 38, 40, 42, 46-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 May 2009 has been entered.

Response to Arguments

The Rejection under 35 U.S.C. §112, first paragraph with regard to the limitation citing a “drug that kills fat cells” has been withdrawn in consideration of applicants amendment to claim 33.

The Rejection under 35 U.S.C. §112, second paragraph is considered but is not found persuasive because claim 33 discloses:

wherein said substance is- ~~a small molecule drug which is: a drug that kills fat~~
methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a
beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor.

Regardless of the amendment, the rejection as already made of record is reapplied because applicant cites a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation in the same claim is considered indefinite. Principally, determination of the metes and bounds of the invention is not clear based upon such

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incongruence. Therefore, for the reasons already made of record, The Rejection under 35 U.S.C. §112, second paragraph is maintained.

The Rejection under 35 U.S.C. §103(a) is averred by applicants because it is alleged that there is no articulated reasoning as to why one of ordinary skill in the art would combine these elements.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, articulated reasoning with some rational underpinning to support the legal conclusion of obviousness has been sufficiently set forth in the said Rejection under 35 U.S.C. §103(a).

The rational underpinning to combine is directed to applicants' limitation in the claim drawn to *comprising* which is broad and is not exclusive. Therefore, the rational underpinning of the rejections already made of record are proper in view of the metes and bounds of the present set of claims. Further, rational underpinning is also directed to the inventive objective of the invention. Essentially, the invention may reasonably encompass obesity but is not exclusive to an obese disorder, hence the limitation “**normal** but *undesired adipose tissue*” in claim 33 and all claims dependent. The limitation “*undesired*” is deemed a matter of perception by the one of skill, since the instant specification is silent as to a definition, description, and/or explanation of

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the term “*undesired*”. Thus, in light of the above, the invention could be reasonably deduced to a subject with normal adipose tissue being injected with a beta adrenergic stimulator (BAS, hereinafter). In consideration of this, the method has a well-defined target population via obviousness in the well-known art of BAS administration.

Specifically, Friedman is averred because it teaches macromolecules and not the compound of the invention. However, Friedman was employed based upon the methods of reducing obesity. In view of this, the absence of a clear teaching of a beta adrenergic stimulator for reducing normal but unwanted adipose tissue is reconsidered but is not found persuasive because Friedman et al. essentially teach the basic elements in obviousness over the claimed invention. Specifically, as will be cited in the references that follow, the one of skill would have recognized that in the art of pharmaceutical technology that surface area is of paramount importance in the way of ensuring more therapeutic bioavailability of the drug. It is well-established in the art that injectable dosage forms such as the one of the claimed invention initially would have had to test microparticles through routine experimentation in the way of developing macromolecules. Further, Friedman et al. teach embodiments which clearly extend and encompass the claimed invention drawn to variable ingredients/components that may be included in most injectable dosage forms. Reasoning as to why it would be obvious to try variable forms of carriers/excipients/adjuvants is well established in the art of pharmaceutical technology. Absent of any specific reasoning in the specification that distinguishes this current invention because of the limitations of claim 33, the one of skill could reasonably conclude that the utilization of microparticles are necessary based upon the need for a greater surface area for therapeutic effect in the human system. Accordingly, claim 51 is broad and is not exclusive

because of *comprising* language. The deficiencies of Friedman et al. are readily resolved via the references that follow.

Applicants' further aver Greenway '724 based upon the association with Friedman, *supra*. However, that argument is moot because Friedman has been withdrawn and Greenway '724 is still deemed proper in view of claimed invention. Greenway '724 clearly teaches beta adrenergic stimulators incorporated for the treatment of undesired adipose tissue.

Further, applicants' aver Woiszwilllo et al. because it is alleged to teach macromolecules mixed with a polymer. Applicants' see no relation of this in the claimed invention. However, upon further consideration of the said reference in view of applicants' comments, Woiszwilllo et al. is hereby found proper because Woiszwilllo et al. reasonably contemplates microparticles, principally. The reference is proper for what it shows. Accordingly, due to the *comprising* language in the set of claims, the inventive objective of claims is broad and not exclusive in view of the claimed invention. Still further, regardless of the configuration in which PEG is formulated with any bioactive agent in a micro-system for the purposes of therapeutic administration, the one of skill would reasonably expect the same effect therapeutically.

Applicants' further aver Neville Jr. because the reference relates to macromolecules and not small molecules of the claimed invention. However, upon further consideration, Neville Jr. is hereby found proper applied because the one of skill would recognize that the properties of PEG are identical whether combined with a macromolecule or a micromolecule. In most case, through due routine experimentation, the subject molecule may be micronized initially before acquiring macromolecule classification. Further, PEG is art-known and a well-established excipient/carrier

in the field of pharmaceutical technology. Thus, the teachings of Neville Jr., et al would reasonably encompass the limitations of the claimed invention drawn specifically to PEG.

Applicants' do not aver Acharya et al. and for the reasons already made of record, Acharya et al. is hereby maintained.

Applicants' aver Hubell because of the absence of the teaching drawn to a formulation for controlled release of a small molecule substance such as recited in the instant claims. Further, it has no relation to a method for administering such a substance in a controlled release formulation by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced. No connection to the claimed invention is apparent. Upon further consideration of the said reference, Hubell et al. is hereby withdrawn.

Further, applicants' aver Shah et al. because it is alleged that Shah et al. does not provide the suggestion that its materials would be useful in a method for administering a substance as recited in the instant claims. Applicants' arguments are considered but are not found persuasive because Shah et al. essentially teaches microparticles. Applicants' duly admit: Shah does generally discuss a broader applicability, including for small molecules, e.g., col. 4, lines 51-65. Small molecules comprise a huge genus including beta adrenergic stimulators. Thus, Shah is proper for what it shows. The motivation to combine with Greenway and Acharya in obviousness over the claimed invention is evident in Shah which clearly encompasses the variable limitations comprising microparticles and the sustained release form of administration. Accordingly, Shah et al. reasonably teach ways of administration which adequately and sufficiently make obvious the limitations attributed to the same in the current invention.

Status of the Claims

Claims 1-32, 34 -35, 37, 39, 41, and 43-45 are cancelled. Claims 33, 36, 38, 40, 42, and 46-63 are pending for further prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 33 recites the broad recitation wherein said substance is: an alpha-2 adrenergic inhibitor [...]. Within the claim, it also recites specific drug agent, such as methotrexate, which is the narrower statement of the range/limitation in comparison to the specification of certain classifications of drugs also represented such as beta-adrenergic

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stimulators. Specifically, the mixture of broad classifications of drug agents in association with specifically named drug agents is not proper for the purposes indefiniteness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33,36,38,40, 42, 46-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (USPN 6124439), Greenway, III et al. (USPN 4,588,724), Woiszwilllo et al. (USPN 5,981,719) and Neville, Jr. et al. (USPN 5,066,490) in view of Acharya (USPN 5,686,094) and Shah (USPN 6020004).

Friedman et al. teach a method of reducing obesity. The OB polypeptide has significant value for cosmetic use, in addition to the health benefits. In particular, since the OB polypeptides

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of the invention, including derivatives and agonist analogs thereof, are useful for modulation of the rate and quantity of fat cell deposition in an animal, they are useful for reducing unsightly fat tissue, e.g., fat deposits in the abdomen, hips, thighs, neck, and chin that do not necessarily amount to an obese condition, but which nevertheless detract from an individual's appearance. The fat reduction effect is thought to be accomplished, in part, by a reduction in appetite, i.e., a reduction in food intake, by an increase in basal metabolism, or both. Thus, the present OB polypeptide, or its derivatives or agonist analogs, is useful for administration to a subject to effect cosmetic changes in fat tissue deposits, whether by modulating fat deposition, reducing appetite, or both (column 49, lines 23-38).

Friedman et al. teach that [s]uch pharmaceutical compositions may be for administration for **injection**, or for oral, pulmonary, nasal or other forms of administration. In general, comprehended by the invention are pharmaceutical compositions comprising effective amounts of protein or derivative products of the invention together with pharmaceutically acceptable diluents, preservatives, solubilizers, emulsifiers, adjuvants and/or carriers. Such compositions include diluents of various buffer content (e.g., Tris-HCl, acetate, phosphate), pH and ionic strength; additives such as detergents and solubilizing agents (e.g., Tween 80, Polysorbate 80), anti-oxidants (e.g., ascorbic acid, sodium metabisulfite), preservatives (e.g., Thimersol, benzyl alcohol) and bulking substances (e.g., lactose, mannitol); incorporation of the material into particulate preparations of **polymeric compounds such as polylactic acid, polyglycolic acid**, etc. or into liposomes. Hyaluronic acid may also be used. Such compositions may influence the physical state, stability, rate of in vivo release, and rate of in vivo clearance of the present

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proteins and derivatives. The compositions may be prepared in liquid form, or may be in dried powder, such as lyophilized form (column 43, lines 14-38).

Friedman et al. does not teach a controlled release carrier and nor does Friedman et al. teach a beta adrenergic stimulator.

However, Greenway, III et al. teach a treatment for accelerating regional weight reduction in humans, wherein an active ingredient encouraging elimination of fatty deposits, preferably a beta adrenergic stimulator or an alpha-2 adrenergic inhibitor, is selectively delivered to a regional fat deposit prior to commencing or during a general weight control program, whereby body weight is preferentially reduced in the selected area. The **beta adrenergic stimulator**, preferably isoproterenol or forskolin, or the alpha-2 adrenergic inhibitor, preferably yohimbine, or combinations thereof may be delivered by any means accomplishing specific delivery to the selected area, including injection, implantation, and topical application to the skin as in an ointment or crème (abstract only).

Greenway, III et al. teach local delivery to counteract the greater responsiveness of the fat cells in the abdomen to the lipolytic effects of beta adrenergic stimulation. Applicants have found that in vivo selective delivery and application of active ingredients to regional fat deposits can reduce those deposits preferentially during a weight control program. Specifically, local delivery of a beta adrenergic stimulator encourages lipolysis of fat cells which normally undergo lipolysis only slowly. Local delivery of an increased concentration of an alpha-2 adrenergic inhibitor has a similar effect, for the reason that inhibition of lipolysis is blocked. Examples of known beta adrenergic stimulators include, but are not limited to, theophylline, isoproterenol,

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forskolin and epinephrine. Examples of known alpha-2 adrenergic inhibitors include, but are not limited to, yohimbine, rauwolscine, piperoxane, phentholamine and dihydroergotamine.

Greenway, III et al. does not teach a controlled release carrier.

However, Woiszwilllo et al. teach microparticles formed by mixing a macromolecule with a polymer at a pH near the isoelectric point of the macromolecule and incubating the mixture in the presence of an energy source for a predetermined length of time. **The microparticles are composed of homogeneously distributed, intertwined macromolecule and polymer.** Each microparticle allows aqueous fluids to enter and allows solubilized macromolecule and polymer to exit the microparticle and may be formulated to provide a sustained release of macromolecule and polymer from the interior of the microparticle when placed in an appropriate aqueous medium, such as under physiological conditions. Methods of production and methods of use for research, diagnostics and therapeutics are provided (abstract only).

Woiszwilllo et al. does not teach polyethylene glycol group-containing macromolecule specifically.

Woiszwilllo et al. does not adequately teach the specific controlled release carrier which is administered by injection into the adipose tissue at a local area such that sustained release of the substance is effected over at least 3 days by the controlled release carrier and/or where the controlled release carrier provides release of the substance in the local area for a period of 7 to 60 days (claim 58).

However, Neville Jr. et al. teach polyethylene glycol (PEG) [which] has been conjugated to proteins by a variety of procedures to block certain functional domains [...]. **These PEG conjugates can be used to administer an enzyme protein missing from the body in order to**

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correct an enzyme deficiency disease. PEG coupling can minimize two problems, namely, rapid clearance of the unmodified protein from the vascular system, either antibody or extra antibody mediated, and the formation of antibodies to the foreign protein. Rapid clearance and antigenic stimulation are also problems concerning the in vivo use of immunotoxins (column 4, lines 9-22).

Neville Jr. et al. teach multiple polyethylene glycol molecules have been coupled to diphtheria toxin via crosslinker 1. Steric inhibition of toxicity to non-target cells has been achieved (2.5 logs). Studies of hydrolytic rates of release of free diphtheria toxin between pH 5.5 and 6.5 indicate that the dependency on $[H^+]$ is to a power greater than 1.

Neville Jr. et al. teach the crosslinked conjugates of the present invention may be used to prepare prodrugs, which can be used to deliver an amino-group-containing biologically active substance to selected members of a heterogeneous population of cells by exposing the cells to a complex formed by crosslinking the active substance to a cell-binding partner specific for a cell-surface receptor of the selected cells. The compound binds selectively to those cells, and the active substance is released from the complex by exposure to a pH sufficiently low to cleave the crosslinker bond between the active substance and the crosslinker.

Acharya teach controlled release delivery systems suitable for parenteral applications. A variety of sophisticated approaches such as biodegradable implants, liposomes, injectable microspheres, injectable microsponges, and "self depot" injections have been reported in the literature. In all of these types of controlled release delivery systems, there are numerous limitations. A need has existed for delivery systems which can be manufactured easily and administered parenterally using currently available administration systems. With the present

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invention it is possible to design a delivery system which is fluid at the time of injection but polymerizes in the body to form a hydrogel matrix, to achieve controlled release of active ingredients over a period from a *few days to many months* (column 2, lines 20-35).

Acharya also teach and encompass the limitation of claim 56 which is drawn to a controlled release carrier in an amount of from 01. to 20 % by weight. Acharya teach if containing a pharmaceutical agent, [it] will optionally include additional edible non-toxic ingredients as conventionally employed in medicinal dosage forms. **Thus, the compositions of the invention may optionally include one or more excipients in an amount within the range of from about 0.1% to about 99% by weight and preferably from about 1% to about 95% by weight**, such as lactose, sugar, corn starch, modified corn starch, mannitol, sorbitol, artificial sweeteners, and inorganic salts such as calcium carbonate. Other conventional ingredients which may optionally be present include preservatives, stabilizers, plasticizers, cosolvents, anti-adherents or silica flow conditioners or glidants, such as Syloid brand silicon dioxide as well as FD&C colors (column 6, lines 48-61).

However, Shah teaches the methodology and technical embodiments drawn to phase separation techniques. The present invention relates to improved methods of making polymeric microparticles containing a variety of active ingredients, e.g. protein drugs. In addition, the present invention relates to using the above active protein containing polymeric microparticles to prepare compositions for the sustained delivery of the therapeutics (abstract only).

Shah further teaches that the release characteristics for the active ingredient from microparticles prepared by methods such as those described above may be continuous or discontinuous, and in some cases, the initial level of active ingredient release is too high or too

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low. Thus, various additives are often utilized in an attempt to control the release of active ingredient (column 2, lines 26-31).

Thus, the significant advantages of the present processes as compared to the processes described in the art, include for example, 1) ease of manufacture of the active ingredient loaded microparticles; 2) versatility as relates to the class of polymers and/or active ingredients which may be utilized; 3) higher yields and loading efficiencies; and 4) the provision of sustained release formulations that release active, intact active ingredient in vivo, thus providing for controlled release of active ingredient over an extended period of time (e.g. up to 180 days). As used herein the phrase "contained within" denotes a method for formulating an active ingredient into a composition useful for controlled release, over an extended period of time of the active ingredient.

Further, Shah et al. teach in the sustained-release compositions of the present invention, an effective amount of active ingredient will be utilized. As used herein, sustained release refers to the gradual release of active ingredient from the polymer matrix, over an extended period of time. The sustained release can be continuous or discontinuous, linear or non-linear, and this can be accomplished using one or more polymer compositions, drug loadings, selection of excipients (column 7, lines 8-29).

Thus, it would have been prima facie obvious to one of skill at the time of invention to at once recognize with a reasonable expectation of success the inventive objective of the claimed invention based on the incorporating together and/or combining the references of Friedman et al. (USPN 6124439) and Greenway, III et al. (USPN 4,588,724) and Acharya (USPN 5,686,094) in view of Shah (USPN 6020004).

The differences in the prior art and the claims at issue are of no consequence in this instance because each and every reference, based on the same or similar subject matter, resolves the deficiencies of the other by adequately addressing each and every limitation presented by the instant claims. The references *supra* are replete with embodiments which adequately support and suggest the inventive objective of the present invention. Particularly, Neville Jr, et al. provides the essential motivation to formulate an injectable comprised of PEG because it is a hall-mark pharmaceutical carrier used in a myriad of injectable formulations because of its specific properties and characteristics which make the active agent more bioavailable. Acharya provides an encompassing motivation based on subject matter drawn specifically to ranges of formulation percentage dosing which make the range limitations of instant claim 56 obvious. The related subject matter, methods, processes and such modifications shared by all references *supra* in comparison to the inventive objective and central issue of the claimed invention is *prima facie* obvious. The skilled artisan would at once recognize with a reasonable expectation of success that this claimed invention could reasonably be deemed obvious based on the related and overlapping subject matter of Greenway, III et al. (USPN 4,588,724) and Acharya (USPN 5,686,094) in view of Shah (USPN 6020004).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617